

EXHIBIT Q



December 20, 2013

Roger Cameron
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102

RE: *In re: Ethicon, Inc. MDL*

Dear Roger:

Please accept this letter as a follow-up to my letter dated November 11, 2013 in response to your e-mail dated November 4, 2013 seeking a response to 39 requests regarding certain Medscand related documents (the "Requests").

As we have noted previously, Ethicon has undergone efforts to identify and locate Medscand documents that plaintiffs have requested to the extent they are reasonably available. Ethicon has now provided explanations of its efforts in two lengthy letters to Tom Cartmell, on October 11, 2013 and November 5, 2013 respectively. Yet, plaintiffs fail to consider these prior discussions and continue to submit duplicative requests.

In a good faith effort to cooperate with plaintiffs, we provide a response below to each of your 39 requests that identify documents located in connection with our search efforts. We have recently identified documents responsive to one or more of your requests that were not previously produced including new business development documents that were previously withheld as privileged, but upon further consideration, may be produced. These documents are in Production 186, and they are included in the responsive bates ranges identified below.¹

Finally, in our November 5, 2013 correspondence to Tom Cartmell, we noted that there were additional documents related to the product recently identified through Ethicon's affiliate in Scotland that were still being processed for production. They have since been produced, and any documents within that production that are responsive to your requests have been identified below.

Below are specific responses to each of your requests.

¹ Please note that in an effort to produce these documents as soon as possible, they have not been produced in an ESI compliant version. We will produce an ESI compliant version by the end of the year.

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1. PR563-001 Release Authorization for Prolene for use as a hernia mesh or as a pelvic floor implantation a/k/a IVS and/or TVT between 1990 and 2002

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01320124 - ETH.MESH.01320189

2. All Clinical Evaluation Reports submitted as required by EC Directive 93/42/EEC, 14 June 1993 to obtain CE mark authorization for Medscand and/or Ethicon for the IVS and/or TVT products

As previously communicated in our November 5, 2013 letter to Tom Cartmell, TVT classic is a Class IIB product. Class IIB products do not require pre-market approval submissions to either a regulatory agency or to a Notified Body. Instead, a technical file for TVT was created and maintained by the company for auditing by the notified body. Our prior correspondence provides an explanation of the nature and scope of our efforts to locate documents responsive to this request.

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request.

ETH.MESH.01317508 - ETH.MESH.01317613
ETH.MESH.01320124 - ETH.MESH.01320189
ETH.MESH.06661156 - ETH.MESH.06661266
ETH.MESH.07295564 - ETH.MESH.07295655
ETH.MESH.09947883 - ETH.MESH.09947890
ETH.MESH.09947929 - ETH.MESH.09947933
ETH.MESH.09948081 - ETH.MESH.09948119
ETH.MESH.09981041 - ETH.MESH.09981146
ETH.MESH.10444876 - ETH.MESH.10444911
ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10587905 - ETH.MESH.10589323

In addition, as we explained in our November 5th response, Ethicon is in the process of collecting regulatory materials from countries identified by plaintiffs. This list of countries included a number of EU countries. We refer you to our first installment on 11/27/13, and second installment on 12/13/13, as well as their respective cover letters, which cover the majority of EU countries identified. We will produce any additional documents regarding the remainder of the countries identified by Plaintiffs shortly.

3. All Risk Analyses and/or Risk Management Reports, whether denominated as such or as a DDSA, aFMEA, pFMEA, dFMEA or otherwise, for the IVS and/or TVT

products, including but not limited to the following: Analysis made 1998-09-22 by Margareta Eriksson and Tommy Svensson (Preventia AB), system description, attached drawings; Review of analysis 1999-01-27 by Margareta Eriksson and Tommy Svensson (Preventia AB) (Revised TVT-2 device: 5 mm needle, shiny surface, tip angle same as 6 mm; transparent shrink tube, packed in double plastic, handle screw instead of O-ring); Utgava 3 (undated); Utgava 4 1999-06-01 (Genomgang av ME/TS); Utgava 5 1999-06-23 (Ny vardering av risker TS/ME); Review of Risk analysis based surveillance data and complaint statistics 1999 (performed by ME and TS 2002-02-02)

After a reasonable and good faith investigation, we were unable to locate certain analyses and/or revisions referenced in this request specifically, 1998-09-22, 1999-01-27, 2002-02-02, Utgava 3 and Utgava 4. However, we have located Revision 7 of 2000-02-06 which lists 1998-09-22, 1999-01-27, and 2000-02-02 as previous versions. We refer you to the following documents that we believe to be responsive to this request.

ETH.MESH.00302224 - ETH.MESH.00302224
ETH.MESH.00355500 - ETH.MESH.00355516
ETH.MESH.01589812 - ETH.MESH.01589825
ETH.MESH.06661874 - ETH.MESH.06661979
ETH.MESH.06696581 - ETH.MESH.06696581
ETH.MESH.07295564 - ETH.MESH.07295655
ETH.MESH.07351279 - ETH.MESH.07351279
ETH.MESH.07363154 - ETH.MESH.07363154
ETH.MESH.08466860 - ETH.MESH.08466864
ETH.MESH.08466865 - ETH.MESH.08466869
ETH.MESH.08466870 - ETH.MESH.08466875
ETH.MESH.08466955 - ETH.MESH.08466957
ETH.MESH.08770248 - ETH.MESH.08770248
ETH.MESH.09103808 - ETH.MESH.09103813
ETH.MESH.09981041 - ETH.MESH.09981146
ETH.MESH.10180994 - ETH.MESH.10180997
ETH.MESH.10184401 - ETH.MESH.10184408
ETH.MESH.10585559 - ETH.MESH.10585680
ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10591916 - ETH.MESH.10591916
ETH.MESH.10616522 - ETH.MESH.10616627
ETH.MESH.10630841 - ETH.MESH.10632259

We are continuing to search for additional risk management documents including DDSAs, aFMEAs, pFMEAs, and dFMEAs as discussed with plaintiffs' counsel in connection with the 30(b)(6) deposition of Ed Jacobs, and we will produce additional documents we identify.

4. **All reports and underlying data on elongation tests, including but not limited to bi-directional elasticity tests, performed on 6 mil construction Prolene by or on behalf Ulf Ulmsten, Medscand and Ethicon between 1990 and 2002**

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01803974 - ETH.MESH.01804277
ETH.MESH.02181845 - ETH.MESH.02181847
ETH.MESH.02267017 - ETH.MESH.02267023
ETH.MESH.02608122 - ETH.MESH.02608449
ETH.MESH.02613634 - ETH.MESH.02613636
ETH.MESH.06260135 - ETH.MESH.06260438
ETH.MESH.06661980 - ETH.MESH.06662283
ETH.MESH.10587905 - ETH.MESH.10589323

5. **All documents that constitute, refer or relate to any IDE that defendants prepared and/or obtained to provide Prolene mesh to Ulf Ulmsten, any hospital with which he was affiliated, Medscand or any other person between 1990 and 2002**

After a reasonable and good faith investigation, including we are not aware of any IDE associated with TVT products.

6. **All Essential Requirements Checklists and supporting document prepared by defendants, Medscand and/or anyone acting on their behalf**

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10630841 - ETH.MESH.10632259

7. **Any notes, handwritten or electronic, made before, during or after by any member of the due diligence teams for the License and Supply Agreement or the Asset Purchase Agreement that refer or relate to the due diligence performed or approved with respect to those agreements**

Our prior correspondence already explained the nature and scope of due diligence materials identified. After a reasonable and good faith investigation, we refer you to the following documents that we believe to be responsive to this request.

ETH.MESH.08504977 - ETH.MESH.08504979
ETH.MESH.10184401 - ETH.MESH.10184408
ETH.MESH.10185174 - ETH.MESH.10185176
ETH.MESH.10185181 - ETH.MESH.10185185
ETH.MESH.10185187 - ETH.MESH.10185191
ETH.MESH.10185193 - ETH.MESH.10185195
ETH.MESH.10185196 - ETH.MESH.10185199
ETH.MESH.10185201 - ETH.MESH.10185204
ETH.MESH.10185206 - ETH.MESH.10185208
ETH.MESH.10185210 - ETH.MESH.10185212
ETH.MESH.10185346 - ETH.MESH.10185348
ETH.MESH.10185349 - ETH.MESH.10185349
ETH.MESH.10185350 - ETH.MESH.10185354
ETH.MESH.10185397 - ETH.MESH.10185401
ETH.MESH.10185491 - ETH.MESH.10185492
ETH.MESH.10185493 - ETH.MESH.10185496
ETH.MESH.10185497 - ETH.MESH.10185497
ETH.MESH.10185498 - ETH.MESH.10185498
ETH.MESH.10185500 - ETH.MESH.10185502
ETH.MESH.10185503 - ETH.MESH.10185505
ETH.MESH.10185506 - ETH.MESH.10185507
ETH.MESH.10185508 - ETH.MESH.10185512
ETH.MESH.10185527 - ETH.MESH.10185527
ETH.MESH.10185528 - ETH.MESH.10185529
ETH.MESH.10185534 - ETH.MESH.10185535
ETH.MESH.10185609 - ETH.MESH.10185612
ETH.MESH.10185614 - ETH.MESH.10185616
ETH.MESH.10185635 - ETH.MESH.10185635
ETH.MESH.10185638 - ETH.MESH.10185639
ETH.MESH.10185647 - ETH.MESH.10185647
ETH.MESH.10185678 - ETH.MESH.10185680
ETH.MESH.10185696 - ETH.MESH.10185700
ETH.MESH.10185702 - ETH.MESH.10185704
ETH.MESH.10185716 - ETH.MESH.10185718
ETH.MESH.10185720 - ETH.MESH.10185722
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10184377 - ETH.MESH.10184378
ETH.MESH.10184388 - ETH.MESH.10184389
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10632551 - ETH.MESH.10632552
ETH.MESH.10632283 - ETH.MESH.10632287
ETH.MESH.10632288 - ETH.MESH.10632289
ETH.MESH.10632290 - ETH.MESH.10632291
ETH.MESH.10632360 - ETH.MESH.10632360
ETH.MESH.10632590 - ETH.MESH.10632591
ETH.MESH.10632422 - ETH.MESH.10632423

8. All documents that MedScand submitted to any Notified Body, including but not limited to the Danish Notified Body, for the purpose of obtaining a Declaration of Conformity and/or the right to affix the CE Mark to Medscands' IVS and/or TVT product

As previously communicated in our November 5, 2013 letter to Tom Cartmell, TVT classic is a Class IIB product. Class IIB products do not require pre-market approval submissions to either a regulatory agency or to a Notified Body. Instead, it is our understanding that a technical file for TVT was created and maintained by the company for auditing by the notified body. Our prior correspondence provides an explanation of the nature and scope of our efforts to locate documents responsive to this request. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request.

ETH.MESH.10585681 - ETH.MESH.10585860
ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10590016 - ETH.MESH.10590016
ETH.MESH.10590017 - ETH.MESH.10590017
ETH.MESH.10590023 - ETH.MESH.10590026
ETH.MESH.10590027 - ETH.MESH.10590028
ETH.MESH.10590038 - ETH.MESH.10590038
ETH.MESH.10590039 - ETH.MESH.10590039
ETH.MESH.10590040 - ETH.MESH.10590040
ETH.MESH.10590048 - ETH.MESH.10590048

As we explained in our November 5th response, Ethicon is in the process of collecting regulatory materials from countries identified by plaintiffs. This list of countries included a number of EU countries. We refer you to our first installment on 11/27/13, and second installment on 12/13/13, as well as their respective cover letters, which cover the majority of EU countries identified. We will produce any additional documents regarding the remainder of the countries identified by Plaintiffs shortly.

9. Any documents that Ethicon, Inc., Ethicon Scotland or any J&J entity prepared for its own submission of [sic] for anyone else's submission to any Notified Body, including but not limited to the Danish Notified Body, for the purpose of obtaining a Declaration of Conformity and/or the right to affix to the CE Mark to Medscand's IVS and/or TVT Product or any of the manufacturing and development processes related to them

Please refer to our response to Request 8. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request.

ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10590016 - ETH.MESH.10590016
ETH.MESH.10590017 - ETH.MESH.10590017
ETH.MESH.10590023 - ETH.MESH.10590026
ETH.MESH.10590027 - ETH.MESH.10590028
ETH.MESH.10590038 - ETH.MESH.10590038
ETH.MESH.10590039 - ETH.MESH.10590039
ETH.MESH.10590040 - ETH.MESH.10590040
ETH.MESH.10590048 - ETH.MESH.10590048

- 10. The complete Design History File by Medscand, including but not limited to any documents that singly constituted only a part of the contents of the Design History File and/or Technical File, in Swedish for the IVS and/or the TVT that was made available to the Acquisition Due Diligence Team and/or submitted to the Danish Notified Body.**

We recently located a joint Medscand and Ethicon Design History File (DHF) in Germany. We refer you to following documents, and we are continuing to investigate whether there is a DHF solely by Medscand.

ETH.MESH.01317508 - ETH.MESH.01317613
ETH.MESH.02178565 - ETH.MESH.02178603
ETH.MESH.06661835 - ETH.MESH.06661873
ETH.MESH.09908307 - ETH.MESH.09908345
ETH.MESH.09948081 - ETH.MESH.09948119
ETH.MESH.09981001 - ETH.MESH.09981039
ETH.MESH.10184401 - ETH.MESH.10184408
ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323

- 11. The English and French translations of that Design History File and/or its constituent parts**

We recently located a joint Medscand and Ethicon Design History File (DHF) in Germany. Portions of the joint DHF are in English, and we refer you to the corresponding bates ranges below. However, we have not located full English or French translations of the joint DHF. We are continuing to investigate whether there is a DHF solely by Medscand, and if so, whether there are full English and French translations of that DHF.

ETH.MESH.01316727 - ETH.MESH.01316765
ETH.MESH.01317508 - ETH.MESH.01317613
ETH.MESH.02178565 - ETH.MESH.02178603

ETH.MESH.06661835 - ETH.MESH.06661873
 ETH.MESH.09908307 - ETH.MESH.09908345
 ETH.MESH.09948081 - ETH.MESH.09948119
 ETH.MESH.09981001 - ETH.MESH.09981039
 ETH.MESH.10586745 - ETH.MESH.10586939
 ETH.MESH.10586940 - ETH.MESH.10587904
 ETH.MESH.10587905 - ETH.MESH.10589323

12. All specifications for the IVS and/or TVT products and system components in effect at Medscand when Ethicon entered into negotiations with Medscand which culminated in the parties' License and Supply Agreement

Our prior correspondence already explained the nature and scope of due diligence materials identified. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.08696056 - ETH.MESH.08696083
 ETH.MESH.09746920 - ETH.MESH.09746947
 ETH.MESH.09947944 - ETH.MESH.09947954
 ETH.MESH.10184174 - ETH.MESH.10184174
 ETH.MESH.10184175 - ETH.MESH.10184175
 ETH.MESH.10184176 - ETH.MESH.10184176
 ETH.MESH.10184177 - ETH.MESH.10184177
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 ETH.MESH.10184187 - ETH.MESH.10184188
 ETH.MESH.10184189 - ETH.MESH.10184189
 ETH.MESH.10184190 - ETH.MESH.10184190
 ETH.MESH.10184191 - ETH.MESH.10184191
 ETH.MESH.10184192 - ETH.MESH.10184192
 ETH.MESH.10184193 - ETH.MESH.10184193
 ETH.MESH.10184194 - ETH.MESH.10184194
 ETH.MESH.10184195 - ETH.MESH.10184195
 ETH.MESH.10184196 - ETH.MESH.10184196
 ETH.MESH.10184197 - ETH.MESH.10184197
 ETH.MESH.10184198 - ETH.MESH.10184198

ETH.MESH.10184199 - ETH.MESH.10184199
 ETH.MESH.10184200 - ETH.MESH.10184200
 ETH.MESH.10184201 - ETH.MESH.10184201
 ETH.MESH.10184401 - ETH.MESH.10184408
 ETH.MESH.10184678 - ETH.MESH.10184678
 ETH.MESH.10184679 - ETH.MESH.10184679
 ETH.MESH.10184680 - ETH.MESH.10184680
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 ETH.MESH.10184738 - ETH.MESH.10184738
 ETH.MESH.10184739 - ETH.MESH.10184739
 ETH.MESH.10184740 - ETH.MESH.10184740
 ETH.MESH.10184741 - ETH.MESH.10184741
 ETH.MESH.10185633 - ETH.MESH.10185633
 ETH.MESH.10587905 - ETH.MESH.10589323
 ETH.MESH.10632264 - ETH.MESH.10632264
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 ETH.MESH.10632267 - ETH.MESH.10632267
 ETH.MESH.10632274 - ETH.MESH.10632274
 ETH.MESH.10632277 - ETH.MESH.10632277
 ETH.MESH.10632278 - ETH.MESH.10632278

13. All documents that constitute, refer or relate to any agreement between Ulmsten and Medscand, pursuant to which Ulmsten licensed Medscand to manufacture and/or market Ulmsten's patented medical device known as IVS and/or TVT

Our prior correspondence already explained the nature and scope of due diligence materials identified including our efforts to locate any applicable licensing and/or consulting agreements. As stated previously, Ethicon has already identified February 13, 1997 and November 15, 1999 Consulting Agreements with Professor Ulmsten, and the Licensing and Acquisition Agreements with Medscand. We previously stated that we are continuing to search for the March 26, 1999 Consulting Agreement between Ethicon SAS (France) and Professor Ulmsten. We have now located a signed version of this agreement, which is included in the bates ranges identified below. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10185421 - ETH.MESH.10185422
 ETH.MESH.10185440 - ETH.MESH.10185440
 ETH.MESH.10185443 - ETH.MESH.10185443
 ETH.MESH.10185444 - ETH.MESH.10185444
 ETH.MESH.10185445 - ETH.MESH.10185445
 ETH.MESH.10185447 - ETH.MESH.10185447
 ETH.MESH.10185449 - ETH.MESH.10185450
 ETH.MESH.10185451 - ETH.MESH.10185453
 ETH.MESH.10185454 - ETH.MESH.10185454
 ETH.MESH.10185455 - ETH.MESH.10185455
 ETH.MESH.10632268 - ETH.MESH.10632268
 ETH.MESH.10632268 - ETH.MESH.10632268
 ETH.MESH.10632283 - ETH.MESH.10632287
 ETH.MESH.10632290 - ETH.MESH.10632291
 ETH.MESH.10632300 - ETH.MESH.10632300
 ETH.MESH.10632301 - ETH.MESH.10632301
 ETH.MESH.10632360 - ETH.MESH.10632360
 ETH.MESH.10632361 - ETH.MESH.10632361
 ETH.MESH.10632362 - ETH.MESH.10632363
 ETH.MESH.10632364 - ETH.MESH.10632368
 ETH.MESH.10632369 - ETH.MESH.10632372
 ETH.MESH.10632373 - ETH.MESH.10632373
 ETH.MESH.10632402 - ETH.MESH.10632405
 ETH.MESH.10632406 - ETH.MESH.10632407
 ETH.MESH.10632569 - ETH.MESH.10632569

14. All correspondence between Medscand and JnJ that refers or relates to the License and Supply Agreement and/or the Asset Purchase Agreement and any due diligence performed in relation to those agreements

Our prior correspondence already explained the nature and scope of due diligence materials identified. We refer you to Appendix A for the documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

15. All financial statements, balance sheets and projections, whether certified or not, audited or not, of Medscand between the years 1995 and 2002

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are continuing to investigate the location of other financial documents, and we will produce additional responsive documents, if any, that are located.

ETH.MESH.09747139 - ETH.MESH. 09747143
ETH.MESH.09747017 - ETH.MESH. 09747025
ETH.MESH.09747026 - ETH.MESH. 09747036
ETH.MESH.10184285 - ETH.MESH.10184290

16. All documents or copies of documents that Ethicon obtained from Medscand, its officers and authorized representatives during Ethicon's due diligence investigations performed in relation to the License and Supply Agreement and the Asset Purchase Agreement

Our prior correspondence already explained the nature and scope of due diligence materials identified. We refer you to Appendix B for the documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

17. All motions, resolutions, minutes, authorizations, powers of attorney and/or documents evidencing or referring or relating to any corporate action by Ethicon in response to requests to enter into the License and Supply Agreement and/or the Asset Purchase Agreement

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.04193990 - ETH.MESH.04193993
ETH.MESH.10184271 - ETH.MESH.10184271
ETH.MESH.10184272 - ETH.MESH.10184273
ETH.MESH.10184274 - ETH.MESH.10184274
ETH.MESH.10184275 - ETH.MESH.10184275
ETH.MESH.10184276 - ETH.MESH.10184276
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ETH.MESH.10184278 - ETH.MESH.10184278

ETH.MESH.10184279 - ETH.MESH.10184279
ETH.MESH.10184280 - ETH.MESH.10184281
ETH.MESH.10184371 - ETH.MESH.10184373
ETH.MESH.10184377 - ETH.MESH.10184378
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ETH.MESH.10184387 - ETH.MESH.10184387
ETH.MESH.10184388 - ETH.MESH.10184389
ETH.MESH.10184390 - ETH.MESH.10184390
ETH.MESH.10184412 - ETH.MESH.10184412
ETH.MESH.10184904 - ETH.MESH.10184907
ETH.MESH.10185027 - ETH.MESH.10185088
ETH.MESH.10185090 - ETH.MESH.10185106
ETH.MESH.10185107 - ETH.MESH.10185119
ETH.MESH.10185120 - ETH.MESH.10185134
ETH.MESH.10185157 - ETH.MESH.10185166
ETH.MESH.10185219 - ETH.MESH.10185241
ETH.MESH.10185252 - ETH.MESH.10185275
ETH.MESH.10185319 - ETH.MESH.10185341
ETH.MESH.10185346 - ETH.MESH.10185348
ETH.MESH.10185661 - ETH.MESH.10185664
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10632283 - ETH.MESH.10632287
ETH.MESH.10632288 - ETH.MESH.10632289
ETH.MESH.10632295 - ETH.MESH.10632297
ETH.MESH.10632422 - ETH.MESH.10632423
ETH.MESH.10632548 - ETH.MESH.10632548
ETH.MESH.10632549 - ETH.MESH.10632549
ETH.MESH.10632550 - ETH.MESH.10632550
ETH.MESH.10632551 - ETH.MESH.10632552
ETH.MESH.10632590 - ETH.MESH.10632591
ETH.MESH.10632604 - ETH.MESH.10632607

18. The English-language Index of Medscand's Design Control Quality Systems

We would appreciate any further information as to the nature of this request, specifically the collection of documents that the index would pertain to. To the extent this request is based on a document that references the index, please identify that document.

19. All reports prepared by anyone in Ethicon's Medical Affairs department that refer or relate to the License and Supply Agreement and/or the Asset Purchase Agreement

Our prior correspondence explained the nature and scope of due diligence materials identified in conjunction with the License and Supply Agreement and/or the Asset Purchase Agreement. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.03909935 - ETH.MESH.03909936
ETH.MESH.03932912 - ETH.MESH.03932914
ETH.MESH.04384763 - ETH.MESH.04384775

20. All documents that constitute, refer or relate to work instructions in affect at Medscand before and/or after the execution of the License and Supply Agreement

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.07425267 - ETH.MESH.07425268
ETH.MESH.08894429 - ETH.MESH.08894431
ETH.MESH.08894432 - ETH.MESH.08894432
ETH.MESH.08894433 - ETH.MESH.08894434
ETH.MESH.08894436 - ETH.MESH.08894436
ETH.MESH.10184401 - ETH.MESH.10184408
ETH.MESH.10184412 - ETH.MESH.10184412
ETH.MESH.10185374 - ETH.MESH.10185375
ETH.MESH.10185376 - ETH.MESH.10185376
ETH.MESH.10185513 - ETH.MESH.10185513
ETH.MESH.10185720 - ETH.MESH.10185722
ETH.MESH.10185723 - ETH.MESH.10185723

21. All documents that indicate the person who Ethicon made responsible for reviewing Risk Assessment/Design Control Processes and Medical Device Vigilance Reports in connection with the due diligence performed with respect to the License and Supply Agreement and/or the Asset Purchase Agreement

It is our understanding that Ethicon did not perform due diligence related to Medical Device Vigilance Reports because Medscand would not have had Medical Device Vigilance Reports prior to the Licensing Agreement. We have, however, identified documents that address the responsibility of certain individuals in connection with Regulatory Affairs and Quality Systems due diligence. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10184398 - ETH.MESH.10184400
ETH.MESH.10184401 - ETH.MESH.10184408

ETH.MESH.10185206 - ETH.MESH.10185208
ETH.MESH.10185359 - ETH.MESH.10185361
ETH.MESH.10185374 - ETH.MESH.10185375
ETH.MESH.10185376 - ETH.MESH.10185376
ETH.MESH.10185385 - ETH.MESH.10185387
ETH.MESH.10185397 - ETH.MESH.10185401
ETH.MESH.10185482 - ETH.MESH.10185485
ETH.MESH.10185486 - ETH.MESH.10185490
ETH.MESH.10185500 - ETH.MESH.10185502
ETH.MESH.10185503 - ETH.MESH.10185505
ETH.MESH.10185508 - ETH.MESH.10185512
ETH.MESH.10185513 - ETH.MESH.10185513
ETH.MESH.10185514 - ETH.MESH.10185516
ETH.MESH.10185528 - ETH.MESH.10185529
ETH.MESH.10185720 - ETH.MESH.10185722
ETH.MESH.10185723 - ETH.MESH.10185723
ETH.MESH.10632260 - ETH.MESH.10632263

22. All documents that memorialize, refer or relate to Ethicon's assessment of the product liability exposure that was associated with its purchase of the IVS and/or TVT system from Medscand and what insurance and/or litigation reserves Medscand had to indemnify itself for such exposure

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10184432 - ETH.MESH.10184550
ETH.MESH.10184625 - ETH.MESH.10184625
ETH.MESH.10185350 - ETH.MESH.10185354
ETH.MESH.10185377 - ETH.MESH.10185381
ETH.MESH.10185397 - ETH.MESH.10185401
ETH.MESH.10185482 - ETH.MESH.10185485
ETH.MESH.10185486 - ETH.MESH.10185490
ETH.MESH.10185508 - ETH.MESH.10185512
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10632283 - ETH.MESH.10632287
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10632283 - ETH.MESH.10632287

23. Any drafts of and the final report of Quality Systems concerning its due diligence investigation of Medscand in connection with the License and Supply Agreement and/or the Asset Purchase Agreement

Our prior correspondence explained the nature and scope of due diligence materials identified in conjunction with the License and Supply Agreement and/or the Asset Purchase Agreement. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01317508 - ETH.MESH.01317613
 ETH.MESH.10184398 - ETH.MESH.10184400
 ETH.MESH.10184401 - ETH.MESH.10184408
 ETH.MESH.10185210 - ETH.MESH.10185212
 ETH.MESH.10185213 - ETH.MESH.10185213
 ETH.MESH.10185346 - ETH.MESH.10185348
 ETH.MESH.10185374 - ETH.MESH.10185375
 ETH.MESH.10185376 - ETH.MESH.10185376
 ETH.MESH.10185506 - ETH.MESH.10185507
 ETH.MESH.10185513 - ETH.MESH.10185513
 ETH.MESH.10185720 - ETH.MESH.10185722
 ETH.MESH.10185723 - ETH.MESH.10185723
 ETH.MESH.10591601 - ETH.MESH.10591607

24. Any documents that memorialize, refer or relate to your statement in Eth.Mesh.09747933 that IVS or TVT was, “Suitable for 80% of S.U.I. incontinent patient[s]”

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10185219 - ETH.MESH.10185241
 ETH.MESH.10185252 - ETH.MESH.10185275
 ETH.MESH.10185319 - ETH.MESH.10185341

25. All documents that memorialize, refer or relate to any and all payments, contingent or not, made to Medscand and/or Ulmsten in connection with the License and Supply Agreement and/or the Asset Purchase Agreement

Our prior correspondence explained the nature and scope of due diligence materials identified in conjunction with the License and Supply Agreement and/or the Asset Purchase Agreement. In particular, Ben Watson’s correspondence dated September 10, 2013 and November 12, 2013 set forth bates ranges of documents relevant to payments to Professor Ulmsten and Medscand, and we refer you to those letters. We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.09747175 - ETH.MESH.09747175	ETH.MESH.09747370 - ETH.MESH.09747370
ETH.MESH.09747176 - ETH.MESH.09747176	ETH.MESH.09747493 - ETH.MESH.09747495
ETH.MESH.09747177 - ETH.MESH.09747210	ETH.MESH.09747496 - ETH.MESH.09747496
	ETH.MESH.09747497 - ETH.MESH.09747497

ETH.MESH.09747498 - ETH.MESH.09747500
 ETH.MESH.09747501 - ETH.MESH.09747501
 ETH.MESH.09747502 - ETH.MESH.09747504
 ETH.MESH.09747538 - ETH.MESH.09747572

ETH.MESH.09747644 - ETH.MESH.09747645
 ETH.MESH.09747646 - ETH.MESH.09747646
 ETH.MESH.09747647 - ETH.MESH.09747647
 ETH.MESH.09747648 - ETH.MESH.09747649
 ETH.MESH.09748854 - ETH.MESH.09748858
 ETH.MESH.10150870 - ETH.MESH.10150870
 ETH.MESH.10182061 - ETH.MESH.10182065
 ETH.MESH.10183827 - ETH.MESH.10183827
 ETH.MESH.10183843 - ETH.MESH.10183846
 ETH.MESH.10184262 - ETH.MESH.10184262
 ETH.MESH.10184274 - ETH.MESH.10184274
 ETH.MESH.10184366 - ETH.MESH.10184367
 ETH.MESH.10184371 - ETH.MESH.10184373
 ETH.MESH.10184379 - ETH.MESH.10184379
 ETH.MESH.10184390 - ETH.MESH.10184390
 ETH.MESH.10184429 - ETH.MESH.10184429
 ETH.MESH.10184430 - ETH.MESH.10184430
 ETH.MESH.10184431 - ETH.MESH.10184431
 ETH.MESH.10184553 - ETH.MESH.10184573
 ETH.MESH.10184624 - ETH.MESH.10184624
 ETH.MESH.10184626 - ETH.MESH.10184651
 ETH.MESH.10184652 - ETH.MESH.10184656
 ETH.MESH.10184747 - ETH.MESH.10184749
 ETH.MESH.10184750 - ETH.MESH.10184750

ETH.MESH.10184751 - ETH.MESH.10184751
 ETH.MESH.10184752 - ETH.MESH.10184752
 ETH.MESH.10184753 - ETH.MESH.10184754
 ETH.MESH.10184755 - ETH.MESH.10184755
 ETH.MESH.10184756 - ETH.MESH.10184756
 ETH.MESH.10184757 - ETH.MESH.10184758
 ETH.MESH.10184759 - ETH.MESH.10184785
 ETH.MESH.10184792 - ETH.MESH.10184792
 ETH.MESH.10184793 - ETH.MESH.10184793
 ETH.MESH.10184794 - ETH.MESH.10184814
 ETH.MESH.10184821 - ETH.MESH.10184825
 ETH.MESH.10184830 - ETH.MESH.10184849
 ETH.MESH.10184850 - ETH.MESH.10184876
 ETH.MESH.10184898 - ETH.MESH.10184899
 ETH.MESH.10184900 - ETH.MESH.10184900
 ETH.MESH.10184901 - ETH.MESH.10184901
 ETH.MESH.10184902 - ETH.MESH.10184903
 ETH.MESH.10184922 - ETH.MESH.10184927
 ETH.MESH.10185090 - ETH.MESH.10185106
 ETH.MESH.10281917 - ETH.MESH.10281917
 ETH.MESH.10281918 - ETH.MESH.10281963
 ETH.MESH.10477904 - ETH.MESH.10477910
 ETH.MESH.10491959 - ETH.MESH.10491963
 ETH.MESH.10491966 - ETH.MESH.10491967
 ETH.MESH.10527418 - ETH.MESH.10527468
 ETH.MESH.10527471 - ETH.MESH.10527475
 ETH.MESH.10550569 - ETH.MESH.10550569
 ETH.MESH.10550570 - ETH.MESH.10550632
 ETH.MESH.10574915 - ETH.MESH.10574952
 ETH.MESH.10632290 - ETH.MESH.10632291

26. All documents that memorialize, refer or relate to any assignments by Medscand to Ethicon of any supply agreement with Medscand and its contractors and suppliers

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10184432 - ETH.MESH.10184550
 ETH.MESH.10184587 - ETH.MESH.10184587
 ETH.MESH.10184588 - ETH.MESH.10184588
 ETH.MESH.10184589 - ETH.MESH.10184589
 ETH.MESH.10184706 - ETH.MESH.10184707
 ETH.MESH.10184708 - ETH.MESH.10184708
 ETH.MESH.10185370 - ETH.MESH.10185373
 ETH.MESH.10185594 - ETH.MESH.10185596
 ETH.MESH.10185614 - ETH.MESH.10185616

ETH.MESH.10632302 -ETH.MESH.10632303
ETH.MESH.10632410 - ETH.MESH.10632411
ETH.MESH.10632416 - ETH.MESH.10632417
ETH.MESH.10632420 -ETH.MESH.10632420
ETH.MESH.10632421 - ETH.MESH.10632421
ETH.MESH.10632551 - ETH.MESH.10632552

- 27. All documents that memorialize, refer or relate to any due diligence performed on inventory, raw material and/or work in process that Medscand had when Ethicon and Medscand first negotiated the License and Supply Agreement, entered into the License and Supply Agreement, first negotiated the Asset Purchase Agreement and entered into the Asset Purchase Agreement**

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01317508 - ETH.MESH.01317613
ETH.MESH.10184398 - ETH.MESH.10184400
ETH.MESH.10184401 - ETH.MESH.10184408
ETH.MESH.10184418 - ETH.MESH.10184418
ETH.MESH.10184419 - ETH.MESH.10184423
ETH.MESH.10185174 - ETH.MESH.10185176
ETH.MESH.10185181 - ETH.MESH.10185185
ETH.MESH.10185201 - ETH.MESH.10185204
ETH.MESH.10185346 - ETH.MESH.10185348
ETH.MESH.10185362 - ETH.MESH.10185365
ETH.MESH.10185366 - ETH.MESH.10185369
ETH.MESH.10185482 - ETH.MESH.10185485
ETH.MESH.10185508 - ETH.MESH.10185512
ETH.MESH.10185614 - ETH.MESH.10185616
ETH.MESH.10185617 - ETH.MESH.10185617
ETH.MESH.10185618 - ETH.MESH.10185618
ETH.MESH.10185619 - ETH.MESH.10185619
ETH.MESH.10185620 - ETH.MESH.10185620
ETH.MESH.10185621 - ETH.MESH.10185621
ETH.MESH.10185635 - ETH.MESH.10185635
ETH.MESH.10185648 - ETH.MESH.10185650
ETH.MESH.10185651 - ETH.MESH.10185653
ETH.MESH.10185706 - ETH.MESH.10185709

- 28. All drawings of needle tip designs obtained from Medscand, which designs were intended to prevent any bladder perforation during the implantation of the IVS and/or the TVT**

Without conceding the characterization of the intent described in this request, we refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01317508 - ETH.MESH.01317613
 ETH.MESH.05613365 - ETH.MESH.05613365
 ETH.MESH.05852938 - ETH.MESH.05852938
 ETH.MESH.05876008 - ETH.MESH.05876017
 ETH.MESH.05876032 - ETH.MESH.05876032
 ETH.MESH.07295564 - ETH.MESH.07295655
 ETH.MESH.07295656 - ETH.MESH.07295781
 ETH.MESH.09947944 - ETH.MESH.09947954
 ETH.MESH.10184183 - ETH.MESH.10184183
 ETH.MESH.10184184 - ETH.MESH.10184184
 ETH.MESH.10184189 - ETH.MESH.10184189
 ETH.MESH.10184190 - ETH.MESH.10184190
 ETH.MESH.10184193 - ETH.MESH.10184193
 ETH.MESH.10184693 - ETH.MESH.10184693
 ETH.MESH.10184697 - ETH.MESH.10184697
 ETH.MESH.10184702 - ETH.MESH.10184702
 ETH.MESH.10184737 - ETH.MESH.10184737
 ETH.MESH.10184738 - ETH.MESH.10184738
 ETH.MESH.10184739 - ETH.MESH.10184739
 ETH.MESH.10184740 - ETH.MESH.10184740
 ETH.MESH.10184741 - ETH.MESH.10184741
 ETH.MESH.10587905 - ETH.MESH.10589323
 ETH.MESH.10589623 - ETH.MESH.10589623
 ETH.MESH.10589762 - ETH.MESH.10589762
 ETH.MESH.10591611 - ETH.MESH.10591611

29. Any documents that memorialize, refer or relate to sterilization, including but not limited to ethylene oxide sterilization of the mesh component of the IVS and/or TVT system by Ethicon, Ltd. (Scotland)

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.01317508 - ETH.MESH.01317613
 ETH.MESH.01320124 - ETH.MESH.01320189
 ETH.MESH.06661874 - ETH.MESH.06661979
 ETH.MESH.07295564 - ETH.MESH.07295655
 ETH.MESH.07295656 - ETH.MESH.07295781
 ETH.MESH.08091819 - ETH.MESH.08091820
 ETH.MESH.09981041 - ETH.MESH.09981146
 ETH.MESH.10445157 - ETH.MESH.10445257

ETH.MESH.10445258 - ETH.MESH.10445379
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10589769 - ETH.MESH.10589769
ETH.MESH.10589939 - ETH.MESH.10589940
ETH.MESH.10591599 - ETH.MESH.10591599

30. The Technical File and/or Design Dossier for the IVS and/or any TVT system that Ethicon compiled after it executed the Asset Purchase Agreement

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.10585681 - ETH.MESH.10585860
ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10586940 - ETH.MESH.10587904
ETH.MESH.10587905 - ETH.MESH.10589323

31. All Risk Analyses and/or Risk Management Reports, whether denominated as such or as a DDSA, aFMEA, pFMEA, dFMEA or otherwise, for Rigid Catheter Guide, the purchase of which was the subject in part of the Asset Purchase Agreement

Please see our response to Request 3. In addition, we have identified the following previously produced documents that we believe to be responsive to this request.

ETH.MESH.00355500 - ETH.MESH.00355516
ETH.MESH.01589812 - ETH.MESH.01589825
ETH.MESH.06661874 - ETH.MESH.06661979
ETH.MESH.10586745 - ETH.MESH.10586939
ETH.MESH.10616522 - ETH.MESH.10616627

32. Medscand's SOP-04-01

After a reasonable and good faith investigation, we have been unable to locate this document.

33. Medscand's Device Master Record for the IVS and/or TVT systems in their original language and as translated into any other language, including but not limited to English and/or French

As mentioned in our prior correspondence, a Device Master Record ("DMR") is a collection of documents maintained for FDA compliance purposes. Medscand never marketed the TVT product in the United States. We have located one previously produced document (ETH.MESH.10184401 - ETH.MESH.10184408) referring to the need to create a DMR. We are continuing to ascertain whether a DMR was ever created during time frames when Medscand had responsibility for manufacture of the TVT product after the implementation of the 1997

Licensing Agreement and if so, whether those documents exist and are in the possession of Ethicon.

34. All documents that memorialize, refer or relate to Medscand as a certified medical device manufacturer in accordance with ISO 9001 and/or registered with the FDA

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.05642026 - ETH.MESH.05642028
ETH.MESH.06661874 - ETH.MESH.06661979
ETH.MESH.10184432 - ETH.MESH.10184550
ETH.MESH.10184722 - ETH.MESH.10184728
ETH.MESH.10185174 - ETH.MESH.10185176
ETH.MESH.10185206 - ETH.MESH.10185208
ETH.MESH.10185346 - ETH.MESH.10185348
ETH.MESH.10185359 - ETH.MESH.10185361
ETH.MESH.10185385 - ETH.MESH.10185387
ETH.MESH.10185491 - ETH.MESH.10185492
ETH.MESH.10185500 - ETH.MESH.10185502
ETH.MESH.10185503 - ETH.MESH.10185505
ETH.MESH.10185514 - ETH.MESH.10185516
ETH.MESH.10185678 - ETH.MESH.10185680
ETH.MESH.10185716 - ETH.MESH.10185718
ETH.MESH.10587905 - ETH.MESH.10589323
ETH.MESH.10589644 - ETH.MESH.10589644
ETH.MESH.10589651 - ETH.MESH.10589651
ETH.MESH.10589699 - ETH.MESH.10589699
ETH.MESH.10589704 - ETH.MESH.10589704
ETH.MESH.10589764 - ETH.MESH.10589764
ETH.MESH.10589770 - ETH.MESH.10589770
ETH.MESH.10589774 - ETH.MESH.10589775
ETH.MESH.10589867 - ETH.MESH.10589868
ETH.MESH.10589906 - ETH.MESH.10589907
ETH.MESH.10589914 - ETH.MESH.10589914
ETH.MESH.10589921 - ETH.MESH.10589921
ETH.MESH.10589978 - ETH.MESH.10589979
ETH.MESH.10590067 - ETH.MESH.10590068
ETH.MESH.10590070 - ETH.MESH.10590070
ETH.MESH.10632422 - ETH.MESH.10632423

35. All documents that memorialize, refer or relate to any labels that Medscand provided with each sale of any IVS and/or TVT unit

Our prior correspondence explained the nature and scope of due diligence materials identified in conjunction with the License and Supply Agreement and/or the Asset Purchase Agreement. We refer you to Appendix C for the documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

36. All documents the memorialize, refer or relate to any stability studies, materials qualifications, pre-clinical data and/or clinical data that Ethicon obtained from Medscand

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.00999790 - ETH.MESH.00999795
 ETH.MESH.01317508 - ETH.MESH.01317613
 ETH.MESH.01320124 - ETH.MESH.01320189
 ETH.MESH.02594089 - ETH.MESH.02594094
 ETH.MESH.04384763 - ETH.MESH.04384775
 ETH.MESH.06661156 - ETH.MESH.06661266
 ETH.MESH.07295564 - ETH.MESH.07295655
 ETH.MESH.09185745 - ETH.MESH.09185748
 ETH.MESH.09947883 - ETH.MESH.09947890
 ETH.MESH.09947919 - ETH.MESH.09947927
 ETH.MESH.09947929 - ETH.MESH.09947933
 ETH.MESH.09948081 - ETH.MESH.09948119
 ETH.MESH.09981041 - ETH.MESH.09981146
 ETH.MESH.10184975 - ETH.MESH.10184975
 ETH.MESH.10185009 - ETH.MESH.10185009
 ETH.MESH.10185201 - ETH.MESH.10185204
 ETH.MESH.10185362 - ETH.MESH.10185365
 ETH.MESH.10185366 - ETH.MESH.10185369
 ETH.MESH.10185466 - ETH.MESH.10185472
 ETH.MESH.10185711 - ETH.MESH.10185714
 ETH.MESH.10444876 - ETH.MESH.10444911
 ETH.MESH.10445157 - ETH.MESH.10445257
 ETH.MESH.10445258 - ETH.MESH.10445379
 ETH.MESH.10575667 - ETH.MESH.10575705
 ETH.MESH.10575706 - ETH.MESH.10575741
 ETH.MESH.10585422 - ETH.MESH.10585429
 ETH.MESH.10585438 - ETH.MESH.10585445
 ETH.MESH.10585452 - ETH.MESH.10585459
 ETH.MESH.10585468 - ETH.MESH.10585475
 ETH.MESH.10585484 - ETH.MESH.10585491
 ETH.MESH.10585559 - ETH.MESH.10585680
 ETH.MESH.10587905 - ETH.MESH.10589323
 ETH.MESH.10591570 - ETH.MESH.10591570

ETH.MESH.10591571 - ETH.MESH.10591573
ETH.MESH.10632260 - ETH.MESH.10632263
ETH.MESH.10632325 - ETH.MESH.10632325
ETH.MESH.10632326 - ETH.MESH.10632328
ETH.MESH.10632329 - ETH.MESH.10632329
ETH.MESH.10632330 - ETH.MESH.10632339
ETH.MESH.10632340 - ETH.MESH.10632353
ETH.MESH.10632562 - ETH.MESH.10632562
ETH.MESH.10632563 - ETH.MESH.10632563
ETH.MESH.10632567 - ETH.MESH.10632567

37. All documents that are identified in Eth.Mesh.09748342 and in Eth.Mesh.09748347-8 under the heading, “Quality Systems” that Ethicon obtained from Medscand

After a reasonable and good faith investigation, we refer you to the following previously produced document that we believe to be responsive to this request. We are continuing to sources with additional information on quality management materials and will produce any additional responsive documents that are located. **[Rich- I put this in because coming out of our in person meeting, Chuck is looking into quality management so I figured that may lead to more quality systems documents.]** At this time, we refer you to the document below which we believe to be responsive to this request.

ETH.MESH.09748308 - ETH.MESH.09748385

38. All documents that memorialize, refer or relate to the problem described in paragraph 5 of Eth.Mesh.09748379 and Eth.Mesh.09748381 with Ethicon, Inc. (Cornelia) and Ethicon, Ltd. (UK) as the supplier of “polypropylene mesh raw material”, including but not limited to quality characteristics specified by a drawing, any root cause analysis, correction plan, and effectivity analysis

We refer you to the following documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

ETH.MESH.09748308 - ETH.MESH.09748385

39. All documents that memorialize, refer or relate to Ethicon (Scotland) preparing or submitting any documents to the EMEA, Danish Notified Body or any other person, as required by Medical Device Directive 92/42/EEC or any other laws or regulations, to any other foreign government agency or regulatory authority other than the United States for the purpose of obtaining the right to legally market the IVS and/or the TVT

We refer you to Appendix D for the documents identified in connection with our collection efforts which we believe to be responsive to this request. We are presently unaware of other sources for such materials.

We believe that the foregoing responds to Plaintiffs' requests. Please let me know if you wish to discuss these responses.

Sincerely,

BUTLER SNOW LLP

A handwritten signature in black ink, reading "Benjamin M. Watson". The signature is written in a cursive style with a large initial 'B' and 'W'.

Benjamin M. Watson

BMW:fsw

APPENDIX A

14. All correspondence between Medscand and JnJ that refers or relates to the License and Supply Agreement and/or the Asset Purchase Agreement and any due diligence performed in relation to those agreements

ETH.MESH.05972834 - ETH.MESH.05972866
 ETH.MESH.08692946 - ETH.MESH.08692948
 ETH.MESH.08695898 - ETH.MESH.08695930
 ETH.MESH.08695931 - ETH.MESH.08695953
 ETH.MESH.08695954 - ETH.MESH.08695979
 ETH.MESH.08695980 - ETH.MESH.08695984
 ETH.MESH.08695985 - ETH.MESH.08696033
 ETH.MESH.08696034 - ETH.MESH.08696049
 ETH.MESH.08696050 - ETH.MESH.08696055
 ETH.MESH.08696056 - ETH.MESH.08696083
 ETH.MESH.08696084 - ETH.MESH.08696134
 ETH.MESH.08696149 - ETH.MESH.08696151
 ETH.MESH.09746920 - ETH.MESH.09746947
 ETH.MESH.09746948 - ETH.MESH.09746998
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APPENDIX B

16. All documents or copies of documents that Ethicon obtained from Medscand, its officers and authorized representatives during Ethicon's due diligence investigations performed in relation to the License and Supply Agreement and the Asset Purchase Agreement

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APPENDIX C

35. All documents that memorialize, refer or relate to any labels that Medscand provided with each sale of any IVS and/or TVT unit

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APPENDIX D

- 39. All documents that memorialize, refer or relate to Ethicon (Scotland) preparing or submitting any documents to the EMEA, Danish Notified Body or any other person, as required by Medical Device Directive 92/42/EEC or any other laws or regulations, to any other foreign government agency or regulatory authority other than the United States for the purpose of obtaining the right to legally market the IVS and/or the TVT**

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